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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/062,648	01/30/2002	Robert O. Williams III	61113A	2157
109	7590	02/03/2004	EXAMINER	
THE DOW CHEMICAL COMPANY INTELLECTUAL PROPERTY SECTION P. O. BOX 1967 MIDLAND, MI 48641-1967			DOERRLER, WILLIAM CHARLES	
			ART UNIT	PAPER NUMBER
			3744	

DATE MAILED: 02/03/2004 *//*

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/062,648

Applicant(s)

WILLIAMS ET AL.

Examiner

William C Doerfler

Art Unit

3744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-16 and 18-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-16 and 18-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7, 9-16 and 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over the '285 PCT document from the 1-9-2003 IDS in view of Buxton et al.

The '285 PCT document discloses applicants' basic inventive concept, the rapid freezing of effective ingredients including pharmaceuticals in liquid argon or nitrogen (see page 5 lines 21-24), substantially as claimed with the exception of specifying that an insulated nozzle is positioned below the liquid surface (figure 2 appears to show this feature, but it is not well described). Buxton et al discloses a system and method for

freezing pharmaceuticals which atomizes a flow of the pharmaceutical below the liquid level of a cryogen. Buxton does not specifically show an insulated nozzle. However, Buxton does show a nozzle which is heated to prevent the solution from freezing in the nozzle. It would have been obvious to one of ordinary skill in the art at the time of applicants' invention from the teaching of Buxton et al to modify the pharmaceutical freezer of the '285 PCT document by placing the nozzle below the surface of the cryogen to decrease the time required for freezing to ensure high quality, low diameter particles. It is considered obvious to one of ordinary skill in the art that the heater of Buxton could be replaced by an insulated nozzle (depending on the solution being frozen and the cryogen used) while still maintaining the desired effect. In regard to claim 6, all the solvents listed are well known and thus are considered obvious matters of intended use, which could be frozen in the system of Buxton et al without involving any change of structure or inventive step. In regard to claim 7, see column 2 lines 59-66. In regard to claim 9, see line 17 of column 5 of Buxton which states that the nozzle is within applicants' claimed range. In regard to claim 15, Buxton discloses that the particles may need to be dried. Official Notice is taken that fluid bed driers are well known in the art and as such would have been an obvious modification for an ordinary practitioner in the art to provide sufficiently small, dry particles. In regard to claims 18-22, the physical properties of the particles are seen as being matters of design choice which are effected by the substance used to produce the particles. Since applicant has not claimed to produce a new substance, and the structure used to produce the

particles is the same, one of ordinary skill in the art could easily have produced particles within the range claimed using the device described above.

Response to Arguments

Applicant's arguments with respect to claims 1-7,9-16 and 18-22 have been considered but are moot in view of the new ground(s) of rejection. The '285 PCT reference provides the use of liquid argon or nitrogen to rapidly freeze pharmaceuticals.

Conclusion


Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William C Doerrler whose telephone number is (703) 308-0696. The examiner can normally be reached on Monday-Friday 6:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Denise Esquivel can be reached on (703) 308-2597. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


William C Doerrler
Primary Examiner
Art Unit 3744

WCD